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Five-year Results of a Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress Incontinence

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Abstract

Background: Midurethral slings have become the most preferred surgical treatment for female urinary incontinence.
Objective: To compare the efficacy and safety of two midurethral sling procedures with a different technique of sling insertion 5 yr after intervention.
Design, setting, and participants: Multicenter randomized clinical trial conducted in seven public hospitals in Finland including primary cases of stress urinary incontinence.
Intervention: Surgical treatment with the retropubic tension-free vaginal tape (TVT) procedure or the transobturator tension-free vaginal tape (TVT-O) procedure.
Outcome measurements and statistical analysis: Objective treatment success criteria were a negative stress test, a negative 24-h pad test, and no retreatment for stress incontinence. Patient satisfaction was assessed by condition-specific quality-of-life questionnaires.
Results and limitations: A total of 95% of the included women could be assessed according to the protocol 5 yr after surgery. The objective cure rate was 84.7% in the TVT group and 86.2% in the TVT-O group, with no statistical difference between the groups. Subjective treatment satisfaction was 94.2% in the TVT group and 91.7% in the TVT-O group, with no difference between groups. Complication rates were low, with no difference between groups.
Conclusions: Both objective and subjective cure rates were >80% in both groups even when women lost to follow-up were included as failures. The complication rates were low, with no difference between the groups. No late-onset adverse effects of the tape material were seen.
Patient summary: Female urinary stress incontinence can be treated surgically with minimally invasive midurethral sling procedures. Two main approaches of sling placement have been developed: the retropubic and the transobturatory. We compared both approaches and followed the patients for 5 yr. We found no difference in cure rate between the procedures, and patient satisfaction was high.
Trial registration: ClinicalTrials.gov identifier NCT00379314.

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1. Introduction

Urinary incontinence affects an increasing number of aging women worldwide. As many as 20–50% experience urinary incontinence [1,2], a substantial part of which is stress or mixed incontinence, with the potential to be cured by incontinence surgery.

Proof of the efficacy of the midurethral concept [3] of supporting the urethra for treatment of female urinary stress incontinence was presented by Ulmsten et al. in 1996 [4], and it has profoundly changed the surgical practice of treating female stress or mixed urinary incontinence. The tension-free vaginal tape (TVT) procedure, designed to be performed under local anesthesia as day surgery, has become the gold standard of incontinence surgery because of its efficacy, safety, and longevity [5]. A rapid spread of use of the TVT operation throughout the world revealed risks of complications not experienced within the initial trials with a follow-up $\geq$3 yr [6]. Complications such as bladder and bowel perforations led to a modification of the TVT procedure by passing the tape material through the obturator foramen [7,8]. Short-term observational and randomized trials suggest that the transobturator procedure is as effective as the initial retropubic approach [9,10]. Conflicting data exist on the overall risk of complications associated with the two procedures, however. The nature of the complications reported differs between the procedures [11].

In 2004, we initiated a randomized trial comparing the original retropubic TVT operation with the so-called inside-out transobturator operation, the TVT-O procedure, with the aim of finding differences in cure rates and complication rates between the two procedures during long-term follow-up. The immediate postoperative [12], 12-mo [10], and 36-mo [13] follow-up reports of this trial have been published. We report the 5-yr results of this randomized trial.

2. Methods

2.1. Study design

This was a multicenter randomized trial including seven centers in Finland (four university and three central hospitals) comparing the TVT with the TVT-O procedure for the treatment of stress urinary incontinence. Recruitment was performed among women admitted to the hospitals for treatment of stress urinary incontinence. Women were eligible if they had a history of stress urinary incontinence and an indication for surgical treatment of their incontinence, a positive cough stress test performed in a semi-lithotomy sitting position with a comfortably filled bladder (estimated to 200–300 ml), and a Detrusor Instability (overactivity according to the latest International Continence Society terminology) Score (DIS) of $\leq$7. DIS is a validated 10-item questionnaire, with a score of 0–20, to distinguish between stress and urgency incontinence. A score $\leq$7 is representative for stress incontinence [14]. Exclusion criteria are presented in Table 1 including urogenital prolapse more than second grade according to Baden-Walker [15].

The women were randomized into groups using a computer-generated random allocation in a 1:1 ratio in balanced blocks of four. The investigators called an independent randomization center after obtaining written informed consent from the women. The 5-yr follow-up assessment was performed by an independent physician or occasionally by the surgeon together with an independent research nurse. The trial was approved by the Helsinki University Central Hospital ethics committee.

Table 1 – Exclusion criteria

Previous incontinence surgery
Postvoid residual urine volume >100 ml
Urogenital prolapse more than second degree
Body mass index >35 kg/m^2
Active malignancy or previous radiation therapy of the pelvis region
Anticoagulant therapy or hemophilia
Neurogenic disease associated with bladder disorders
Current or more than three urinary tract infections within the past year
Anticholinergic or duloxetine medication

2.2. Study procedures

The midurethral slings used were the TVT and the TVT-O slings (Gynecare, Ethicon, Johnson & Johnson, Somerville, NJ, USA), both introducing the tape starting at the vaginal incision and both using the same macroporous monofilament type 1 polypropylene tape. The operations were performed as originally described by Ulmsten et al. [4] and De Leval [8], respectively. All procedures were performed under local analgesia with light sedation, to keep the patients cooperative. A cough stress test was performed intraoperatively to avoid postoperative voiding difficulties. The tapes were adjusted during vigorous coughs with a bladder filled with 300 ml of saline. At the final adjustment a drop of saline was allowed to escape. Cystoscopy with a 70° optic lens was performed intraoperatively in all cases. No concomitant surgery was performed. The surgeries in all seven participating public hospitals were performed according to the routines of the hospitals. The manufacturer of the slings did not provide any material for the trial and had no part in the planning of the trial, the analysis of the data, or the preparation of the manuscript. The trial was initiated by the responsible researchers and funded solely by governmental research grants.

2.3. Outcomes

The primary outcome was objective and subjective treatment success. Objective success criteria were a negative cough stress test performed in the same manner as required for inclusion into the trial, a negative 24-h pad test (<8 g per 24 h), and no retreatment for stress incontinence. Subjective success or patient satisfaction was assessed by asking if the operation had met their expectations completely, partly, or not at all. Significant improvement in the following condition-specific quality-of-life (QoL) questionnaires: the Urinary Distress Inventory (6 items) (UDI-6) [16], the Incontinence Impact Questionnaire (7 items) [16], the Urinary Incontinence Severity Score [17], and a Visual Analog Scale (VAS) [17], in which 0 represents no urinary problems and 100 unbearable urinary problems, were additionally used as criteria of subjective treatment success.

Complications such as de novo urgency incontinence and/or symptoms, self-reported voiding difficulties, urinary tract infections (UTIs), and tape extrusion or erosion were registered. De novo urgency incontinence was defined as a DIS score >7 and moderate or severe symptoms of urgency associated with urinary leakage in the UDI-6; de novo urgency symptoms were defined as new symptoms of frequency of moderate or severe degree in the UDI-6 and a DIS score >7. Objective signs of voiding difficulties were estimated by postvoid residual (PVR) volumes >100 ml and UTIs by a history of infections treated by antibiotics during the past 2 yr. Tape extrusion or erosion was explored thorough clinical examination including speculum examination in a lithotomy position and careful palpation.

Statistical analysis was performed using SPSS software for Windows v.15.0 (IBM Corp, Armonk, NY, USA). Continuous variables were analyzed with the paired-sample *t* test and the independent-sample *t* test to calculate statistical differences between and within the study groups. The chi-square test was applied for categorical values. A *p* value <0.05 was considered to indicate statistical significance. Sample size calculation was performed assuming a 95% success rate for the TVT procedure and assuming a 10% difference in either success rate or rates of complications would be clinically important. With a 70% power to show a 10% difference, the sample size should be 260 patients with 130 in each group.

3. Results

Between March 2004 and November 2005, 273 women were randomly assigned to either the TVT or the TVT-O procedure. A total of 268 women of the randomized 273 women underwent the allocated operation: 136 TVT operations and 132 TVT-O operations. Four women refused the operation after randomization, and one woman could not participate because she was undergoing surgery unrelated to urogynecologic problems. Figure 1 shows a flowchart of the trial. The baseline demographics were similar between the groups (Table 2).

Overall, 254 women returned to the clinics for their 5-yr follow-up visit. Thus 94.8% of the women (254 of 268) could be assessed per protocol. Fourteen women were not available for assessment: 5 in the TVT group (5 of 136) and 9 in the TVT-O group (9 of 132). One woman had died, two women had moved abroad, six women refused to return to the clinic, and five women had undergone a repeat incontinence operation.

Among the 254 women assessed according to the protocol, 84.7% (111 of 131) in the TVT group had a negative stress test, a negative pad test, and had had no retreatment

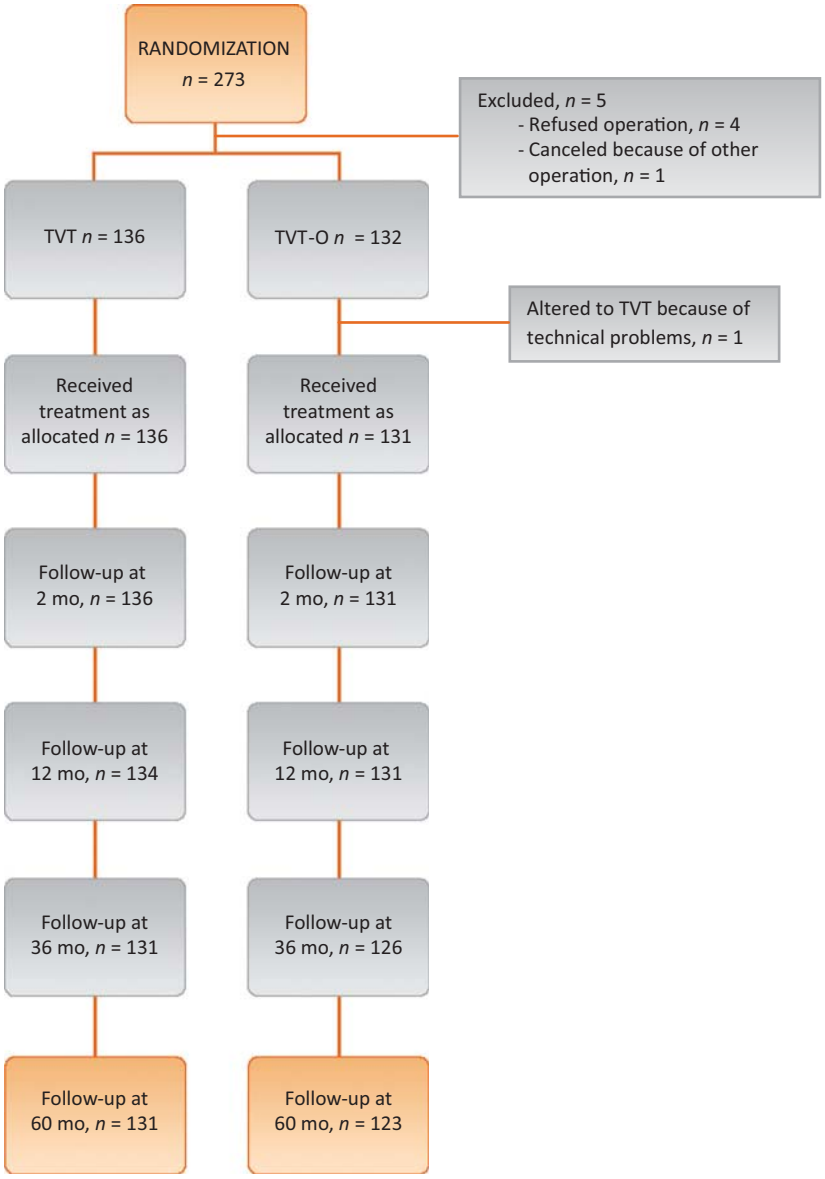

Fig. 1 – Flowchart of the study.
TVT = tension-free vaginal tape; TVT-O = transobturator tension-free vaginal tape.

Table 2 – Patient demographics

	TVT	TVT-O
Age, yr, mean ± SD	53 ± 10	54 ± 10
Parity, median (range)	2 (0–6)	2 (0–7)
Postmenopausal, *n* (%)	71 (52)	78 (60)
HRT, *n* (%) of postmenopausal women	50 (37)	50 (38)
BMI, mean ± SD	26 ± 3	26 ± 4
Hysterectomized, *n* (%)	35 (26)	41 (31)
Previous gynecologic laparotomies, *n* (%)	37 (27)	35 (27)
Previous surgery for prolapse, *n* (%)	7 (5)	12 (9)
Duration of symptoms, yr ± SD	7 ± 6	10 ± 7*
Pad test, g, mean ± SD	44 ± 39	44 ± 48

BMI = body mass index; HRT = hormone replacement therapy; SD = standard deviation; TVT = tension-free vaginal tape; TVT-O = transobturator tension-free vaginal tape.
* $p = 0.0025$.

Table 4 – Preoperative and 5-yr follow-up results of condition-specific quality-of-life questionnaires

	TVT		TVT-O	
	Preoperative (*n* = 136)	5 yr (*n* = 131)	Preoperative (*n* = 132)	5 yr (*n* = 123)
UISS	11 ± 3	1 ± 3*	11 ± 3	1 ± 2*
DIS	4 ± 2	3 ± 3*	4 ± 2	3 ± 3*
VAS	65 ± 20	11 ± 21*	67 ± 21	9 ± 17*
IIQ-7	16 ± 4	8 ± 2*	16 ± 4	8 ± 2*
UDI-6	14 ± 3	8 ± 2*	13 ± 3	8 ± 2*

DIS = Detrusor Instability Score; IIQ-7 = Incontinence Impact Questionnaire (7 items); TVT = tension-free vaginal tape; TVT-O = transobturator tension-free vaginal tape; UDI-6 = Urogenital Distress Inventory (6 items); UISS = Urinary Incontinence Severity Score; VAS = Visual Analog Scale.
Data are expressed as mean plus or minus standard deviation.
* $p < 0.0003$; significant difference compared with preoperative figures.

because of stress incontinence. The corresponding figures for the women in the TVT-O group were 86.2% (106 of 123), respectively; the differences between the groups were not statistically significant. The objective success rate considering all women lost to follow-up as failures were 81.6% (111 of 136) in the TVT group and 80.3% (106 of 132) in the TVT-O group.

Subjective success, expressed as treatment completely meeting expectations, was experienced by 84.6% (115 of 136) in the TVT group and 85.6% (113 of 132) in the TVT-O group. Including even those who thought that expectations had partly been met, the corresponding subjective improvement rates were 94.2% in the TVT group and 91.7% in the TVT-O group (Table 3). A significant improvement from preoperative scores was seen in all condition-specific QoL questionnaires for both groups, with no difference between the groups (Table 4).

De novo urgency incontinence was experienced by 2.8% of the women (7 of 254) at their 5-yr follow-up visit, 3.1% (4 of 131) in the TVT group and 2.4% (3 of 123) in the TVT-O group. Of these seven women, five were using anticholinergic medication, none had a PVR >100 ml, and four women had experienced one or more UTIs (range: 1–9) during the past 2 yr. None of these seven women fulfilled the criteria of urgency incontinence at their 2-mo follow-up visit; one and three women did at the 12-mo and 36-mo visit, respectively. De novo urgency symptoms were recorded in only five women, three of these having de novo urgency incontinence. Frequency and urgency symptoms of moderate or severe degree in the UDI-6 were experienced preoperatively by 28.0% (75 of 268) of the women; only 4.7% (12 of 254) experienced these symptoms at their 5-yr follow-up. Thus 84% of the women were cured of their preoperative urgency symptoms.

Table 3 – Patient satisfaction with the tension-free vaginal tape and the transobturator tension-free vaginal tape operations 5 yr postoperatively

	TVT		TVT-O		
Expectations met:					
Completely	84.6%	115/136	85.6%	113/132	NS
Partly	9.6%	13/136	6.1%	8/132	NS
Not at all	2.2%	3/136	0.8%	1/132	NS
Lost to follow-up	3.7%	5/136	6.8%	9/132	NS
Recommend to a friend:					
Yes	92.6%	126/136	88.6%	117/132	NS
Probably	2.9%	4/136	2.3%	3/132	NS
No	0.7%	1/136	1.5%	2/132	NS
Lost to follow-up	3.7%	5/136	6.8%	9/132	NS

TVT = tension-free vaginal tape; TVT-O = transobturator tension-free vaginal tape.

At least one episode of UTI (range: 1–9) had required treatment with antibiotics in 21.3% (54 of 254) of the women, 20.6% in the TVT and 22.1% in the TVT-O group. Sixteen women (6.3%) had had between three and nine UTIs during the last 2 yr. The mean amount of PVR among these 16 women was ±23.0 ml. Six women (4.6%) in the TVT group and 7 women (5.7%) in the TVT-O group had a PVR >100 ml, mean ±144 ml (range: 107–180) and ±195 ml (range: 125–360), respectively. The mean plus or minus standard deviation amount of PVR was ±24.9 ml in the total population; the mean amount in those who had not experienced a UTI during the last 2 yr was ±26.3 ml (199 of 254). Among those who had had one or more UTI, the PVR was ±19.8 ml (54 of 253).

No woman had any sign of tissue reaction, erosion, or tape protrusion at their 5-yr follow-up. During the course of the study, two women experienced tape problems, both in the TVT-O group. One woman had a tape extrusion 1 yr postoperatively. The midline visible part of the tape was excised, resulting in incontinence, and she later had a TVT operation. One woman had retention problems, and the tape was cut in the midline twice, which resolved the retention, but she experienced urgency symptoms.

4. Discussion

The present long-term follow-up results of our randomized multicenter trial show no difference in objective and subjective success rates between the retropubic and the transobturator approach of placing a midurethral tape for the treatment of female stress urinary incontinence. The strength of this trial is that we were able to asses 95% of the initially enrolled women according to the protocol 5 yr after

surgery. Even when the women lost to follow-up were included in the analysis as treatment failures, the overall success rate for both procedures was >80%. Only two reports randomly comparing retropubic and transobturator midurethral sling procedures, with a follow-up period of 4 yr and 5 yr, respectively [18,19], could be found. Both reports including smaller numbers of women than the present trial found no difference in cure rate between the procedures. The cure rates were slightly lower than in the present trial, which might be explained by the fact that all the surgeons of our trial were experienced specialists who had undergone the systematic nationwide training and certification needed at the time in Finland [20].

Adverse tissue reactions caused by the tape material were not found at the 5-yr visit. New-onset urgency incontinence was seen in <3% of the women. Interesting was the finding that none of the women having urgency incontinence 5 yr after surgery experienced the problem immediately 2 mo after treatment and that only one women had the problem at the 12-mo follow-up and three at the 36-mo follow-up. Another two women had new-onset urgency symptoms without leakage. Noteworthy is the finding that >80% of the women experiencing urgency symptoms preoperatively were relieved of these symptoms 5 yr later. These findings suggest that the risk of developing urgency symptoms with or without leakage after midurethral tape procedure is very low and that actually, as reported earlier, midurethral tape surgery can cure urgency symptoms, the reasons for which remain uncertain [21,22]. A weakness concerning the relevance of these findings is that urodynamics were not performed in these women, and the diagnosis of urgency incontinence is thus based on the subjective perception of the women themselves as registered through the UDI-6 and the DIS questionnaires.

Because invasive urodynamics were not performed, direct objective signs of voiding difficulties at 5 yr after surgery could not be investigated. Indirect signs of bladder emptying problems could be the occurrence of recurrent UTIs and/or PVR >100 ml. Only 6% of the women had three or more UTIs during the past 2 yr; exclusion criteria were more than three UTIs during the past year. The women with three or more UTIs did not differ from those who had not experienced UTI regarding the amount of PVR. All together 13 women had a PVR >100 ml, 2 of these had had a UTI, 5 reported slight but not bothering voiding difficulties, and 6 were completely satisfied with their situation. It therefore seems as if voiding problems and recurrent UTI 5 yr after surgery with midurethral tapes is a rather minor problem. The yearly incidence of UTI in a normal population of the same age as the women of the present trial has been found to be as high as 10–20% [23]. Thus an incidence of 21% during a 2-yr follow-up of the present trial does not differ from the incidence of a normal population.

5. Conclusions

The long-term follow-up results of the present randomized trial comparing the retropubic TVT procedure with the inside-out TVT-O procedure reveals no difference in cure rate or complication rate between the two operations. Both objective and subjective cure rates were >80% in both groups even when women lost to follow-up were included as failures. The complication rates were low with no difference between groups. No late-onset adverse effects of the used tape material were seen.

Author contributions: Carl Gustaf Nilsson had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Laurikainen, Valpas, Nilsson.
Acquisition of data: Laurikainen, Valpas, Aukee, Kivelä, Rinne, Takala, Nilsson.
Analysis and interpretation of data: Laurikainen, Nilsson.
Drafting of the manuscript: Laurikainen, Nilsson.
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